IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
Gainesville Division

CONCORDIA PHARMACEUTICALS INC., S.À.R.L. *Plaintiff*, v. WINDER LABORATORIES, LLC and STEVEN PRESSMAN *Defendants*.	C.A. No. 2:16-cv-00004-RWS Jury Trial Demanded

FIRST AMENDED COMPLAINT

Plaintiff Concordia Pharmaceuticals Inc., S.à.r.l. ("Plaintiff" or "Concordia"), by and through their undersigned counsel, for their First Amended Complaint against Defendant Winder Laboratories, LLC ("Defendant Winder") and Defendant Steven Pressman ("Defendant Pressman" and, collectively, "Winder" or the "Defendants"), hereby alleges and states the following:

NATURE AND BASIS OF ACTION

1. This action arises out of Defendants' knowing and willful false or

misleading, or false and misleading, advertising, marketing, sale and/or promotion of the pharmaceutical products, B-Donna and Phenohytro. Defendants' actions, with respect to B-Donna and Phenohytro, constitute false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); contributory false advertising in violation of Section 43(a)(1)(B) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(B); federal unfair competition in violation of Section 43(a)(1)(A) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A); unfair competition under common law; violation of the Georgia Uniform Deceptive Practices Act, O.C.G.A. § 10-1-372; unjust enrichment in violation of Georgia common law; and tortious interference in violation of Georgia common law. Defendants' actions, with respect to B-Donna, constitute trademark infringement under Section 32 of the Lanham Act, 15 U.S.C. § 1114.

2. Plaintiff seeks temporary, preliminary and permanent injunctive relief; actual damages; punitive damages; and recovery of Plaintiff's costs and reasonable attorneys' fees incurred in connection with this action. Plaintiff also seeks cancellation of Defendants' U.S. Reg. No. 4,883,086 pursuant to 15 U.S.C. § 1119.

THE PARTIES

3. Plaintiff is a *société à responsabilité limitée* incorporated and existing

under the laws of the Grand Duchy of Luxembourg, having its registered office at 8-10, avenue de la Gare, L-1610 Luxembourg and registered with the *Registre de Commerce et des Sociétés*, *Luxembourg* under number B 200344, and having a Barbados branch office located at 5 Canewood Business Centre, St. Michaels, Barbados, BB11005.

4. Upon information and belief, Defendant Winder is a Georgia limited liability company with its principal office at 716 Patrick Industrial Lane, Winder, Georgia 30680, and the manufacturer and labeler of the B-Donna and Phenohytro products. Defendant Winder may be served through its Registered Agent, Incorp Services Inc., at 2000 Riveredge Pkwy NW St. 885, Atlanta, Georgia 30328.

5. Upon information and belief, Defendant Pressman resides at 1303 Wellesley Ave., Los Angeles, California 90025-2058, and is the managing member of Defendant Winder.

JURISDICTION

6. This Court has subject matter jurisdiction over the claims pursuant to 28 U.S.C. §§ 1331 and 1338. The Court also has supplemental jurisdiction over Plaintiff's state and common law claims pursuant to 28 U.S.C. § 1367.

7. Venue is proper in this district pursuant to 28 U.S.C. § 1391. A

substantial part of the events giving rise to the claims against Defendants occurred in this District.

8. This Court has personal jurisdiction over Defendants because Winder is a Georgia limited liability company and Defendants regularly transact business in the State of Georgia. Moreover, Defendants have listed their products for sale in online databases that are used by purchasers of PBA pharmaceuticals in this District, and, accordingly, Defendants have purposefully directed their business activities toward this District. In addition, the Defendants have caused harm to Plaintiff in this District. Through such conduct, Defendants have purposefully availed themselves of the privileges of conducting business in this District, and, when engaging in such conduct, it was reasonably foreseeable that Defendants would be subjected to this Court's jurisdiction.

BACKGROUND FACTS

9. For nearly 80 years, the DONNATAL® brand of pharmaceutical products has helped improve the lives of individuals suffering from irritable bowel syndrome (IBS), a condition characterized by abdominal pain, bloating, and irregular diarrhea or constipation.

10. The DONNATAL pharmaceutical products are a proprietary

combination medicine used as adjunctive therapy in the treatment of IBS and acute enterocolitis. Because DONNATAL products must be used under the supervision of a healthcare provider, they are available by prescription only.

11. DONNATAL products are marketed and distributed by Plaintiff in two unique formulations: (1) immediate release DONNATAL Tablets and (2) fast-acting DONNATAL Elixir, available in either grape or mint flavor (collectively, "DONNATAL").

12. DONNATAL is labeled as containing the following active ingredients in the following strengths: (1) phenobarbital, 16.2 mg; (2) hyoscyamine sulfate, 0.1037 mg; (3) atropine sulfate, 0.0194 mg; and (4) scopolamine hydrobromide; 0.0065.

13. In 1962, when Congress amended the Federal Food, Drug and Cosmetic Act ("FD&C Act"), the Food and Drug Administration ("FDA") was required to conduct a retrospective evaluation of drugs that had previously been approved under the FD&C Act between its enactment in 1938 and 1962. DONNATAL was one of more than 3,400 drugs affected by this amendment. 21 U.SC. § 301 *et seq.*

14. In the 1970s, the FDA began a process of evaluating the safety and

efficacy of these drug products under the Drug Efficacy Study Implementation ("DESI") review program. On June 20, 1978, the FDA required any drugs that were involved in the review process to obtain an approved New Drug Application ("NDA") or an approved Abbreviated New Drug Application ("ANDA") to remain on the market. 43 Fed. Reg. 26,490 (June 20, 1978).

15. On December 30, 1980, Plaintiff's predecessor-in-interest, A.H. Robins Company ("Robins"), obtained conditionally approved ANDAs for its DONNATAL Tablets (ANDA 88-676) and DONNATAL Elixir (ANDA 86-661).

16. Conditionally approved ANDAs have the same status as safety-only NDAs that were approved prior to the 1962 amendments. Drug products manufactured under such a conditionally approved ANDA can be legally marketed until the FDA resolves questions about their effectiveness under the FD&C Act.

17. On May 6, 1983, the FDA published in the Federal Register a notice of an opportunity for a hearing ("NOOH") regarding the regulatory status of PBA drug products, including DONNATAL. Under the FD&C Act, the FDA requires the holders of approved NDAs or those alleging such approvals to submit clinical evidence within 60 days of the NOOH showing that genuine and material issues of

fact exist about the effectiveness of the drug that require an administrative hearing for resolution.

18. Under the NOOH process, only those companies that actively participated in this hearing process were permitted to legally market their PBA drug products. Plaintiff's DONNATAL products have been under this NOOH since 1983, and thus have been allowed to continue to remain on the market pending final resolution of the hearing process. The hearing process has not yet been completed.

19. Upon information and belief, Plaintiff is the only company that continues to participate in the FDA DESI review process for PBA products.

20. In September 2011, the FDA established a Compliance Policy Guide confirming that any drug product coming to market for the first time after September 19, 2011 alleging any legal status under the DESI review was illegal and subject to immediate legal action by the FDA.

21. Accordingly, upon information and belief, Plaintiff is the only company that is legally permitted to market PBA products.

22. Plaintiff maintains contractual relationships with pharmaceutical manufacturers, distributors and/or suppliers in order to make and sell DONNATAL.

These contractual relationships result in economic benefits to Plaintiff, and will continue to do so in the future. These contractual relationships are standard for the industry.

THE DONNATAL MARK

23. The DONNATAL mark is a coined or fanciful mark that is inherently distinctive.

24. Plaintiff and its predecessors-in-interest have continuously used the DONNATAL trademark as the brand name for its line of IBS pharmaceutical products throughout the United States since at least as early as April 1, 1936.

25. All right, title and interest in the DONNATAL mark were assigned to Plaintiff on or around May 15, 2014.

26. Plaintiff and its predecessors-in-interest have engaged in extensive advertising and promotion of the DONNATAL mark to gain goodwill and public recognition of its products. Plaintiff has expended substantial sums of money and resources to advertise and market DONNATAL to wholesalers, distributors, pharmacists, medical professionals, and the consuming public.

27. Plaintiff enjoys a strong reputation and a high level of goodwill among relevant consumers throughout the United States in connection with the products sold under the DONNATAL mark.

28. As a result of Plaintiff's marketing efforts and its long and substantially exclusive use of the mark, the trade and the consuming public identify the DONNATAL mark and the products offered thereunder solely with Plaintiff in this jurisdiction and throughout the United States.

29. The DONNATAL mark was registered by the United States Trademark and Patent Office ("USPTO") as U.S. Reg. No. 338,733 (the "DONNATAL Registration") in connection with "medicinal preparation used in the treatment of gastro-intestinal disturbances" in International Class 5 by Robins on September 15, 1936. A copy of the Certificate of Registration is attached hereto as Exhibit A.

30. The DONNATAL Registration is valid and subsisting, and in full force and effect.

31. All rights in the DONNATAL Registration were assigned to Plaintiff on or around May 15, 2014, the assignment of which has been duly recorded with the USPTO.

32. As such, Plaintiff is the sole owner of the federally-registered and common law trademark rights in the DONNATAL mark for use in connection with pharmaceutical preparations for the treatment of gastro-intestinal diseases.

DEFENDANTS' UNLAWFUL CONDUCT

33. Upon information and belief, Defendant Winder is a Georgia-based contract manufacturer of "generic" drug products.

34. Upon information and belief, Defendant Winder is owned and controlled by Defendant Pressman.

35. Plaintiff is in no way affiliated with Defendants or their related entities.

36. Upon information and belief, Defendants are seeking to exploit the reputation and success of DONNATAL by marketing and selling an unauthorized "generic" version of DONNATAL tablets, first under the name B-Donna, and subsequently under the name Phenohytro.

37. Upon information and belief, Defendants first began planning to manufacture a generic version of DONNATAL in 2013. At that time, the knock-off DONNATAL product was going to be developed and manufactured by Defendants and marketed by another party, Method Pharmaceuticals, LLC ("Method") under the name "Me-PB-Hyos."

38. Following the listing of the Me-PB-Hyos product with Medi-Span and other drug databases, Plaintiff sued Defendants and Method in the Western District of Virginia in *Concordia Pharmaceuticals, Inc. v. Method Pharmaceuticals, LLC et al*, Docket No. 3:14-cv-00016.

39. On March 6, 2015, in an attempt to be dismissed from the litigation, Defendants represented to the Court that they were not manufacturing Me-PB-Hyos or any other DONNATAL equivalent for Method and that they had not participated in the copying of DONNATAL labels.

40. Defendants were subsequently dismissed from that action for lack of jurisdiction on July 1, 2015.

41. Upon information and belief, at the same time they were making these representations to Plaintiff and the Court, Defendants were actively taking steps to manufacture and sell a generic version of DONNATAL.

42. On February 27, 2015, Defendants filed an intent-to-use federal trademark application, Application Serial No. 86/549,114 (the "Application"), to register the mark B-Donna in connection with "Pharmaceutical preparations and substances for the treatment of gastro-intestinal diseases" in International Class 5.

43. On October 15, 2015, Defendants filed a Statement of Use with the USPTO in connection with the Application, claiming first use of the B-Donna mark anywhere on February 14, 2015 and first use in commerce on March 10, 2015.

44. On January 5, 2016, the Application matured into registration under U.S. Reg. No. 4,883,086. A copy of the Certificate of Registration for the B- Donna mark is attached hereto as Exhibit B.

45. Upon information and belief, although Defendant Pressman swore to the USPTO that Defendant Winder had been using the B-Donna mark in commerce since at least as early as March 10, 2015, Defendants did not obtain a National Drug Code ("NDC") number for any B-Donna product until December 2015.

46. On or around December 2015, Defendants obtained National Drug Code ("NDC") numbers for both 100 count and 1000 count bottles of B-Donna products.

47. Upon information and belief, after obtaining the NDC codes, Defendants listed the B-Donna pharmaceutical products with FDA and subscription pharmaceutical drug databases, including Medi-Span and First DataBank (collectively, the "Drug Databases"), on or around January 2016.

48. Upon information and belief, on or around January 2016, a listing for the B-Donna product appeared on the FDA website, DailyMed, with a marketing start date of December 30, 2015.

49. Copies of the B-Donna labels and package inserts were also available on the DailyMed website.

50. Upon information and belief, listings for Defendants' B-Donna products also appeared on the Drug Databases on or around January 2016. A copy of the Medi-Span listing is attached as Exhibit C.

51. Upon information and belief, Defendants' B-Donna products also appear on the pharmaceutical dispensing software of major pharmacies, including CVS and RiteAid.

52. Upon information and belief, B-Donna appears on insurance formularies as an FDA-approved generic that is substitutable for DONNATAL. A copy of an insurance formulary listing B-Donna as an FDA approved generic for DONNATAL is attached as Exhibit D.

53. Upon information and belief, Defendants' have removed their B-Donna listings from the FDA website, DailyMed, however B-Donna remains listed

on the Drug Databases, pharmaceutical dispensing software, and insurance formularies.

54. On or around February 2016, Defendants obtained National Drug Code ("NDC") numbers for both 100 count and 1000 count bottles of Phenohytro products.

55. Upon information and belief, Defendants listed the Phenohytro product with FDA and the Drug Databases, on or around February 2016. A copy of the Medi-Span listing is attached as Exhibit E.

56. Upon information and belief, on or around February 2016, a listing for the Phenohytro product appeared on the FDA website, DailyMed, with a marketing start date of February 29, 2016.

57. Copies of the Phenohytro labels and package inserts are also available on the DailyMed website. A copy of a label and package insert for Phenohytro from the DailyMed website is attached as Exhibit F.

58. Upon information and belief, DailyMed added the disclaimer stating "This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here" to the package insert.

59. Upon information and belief, listings for Defendants' Phenohytro products also appeared on the Drug Databases on or around February 2016.

60. Upon information and belief, Defendants' Phenohytro product also appears on the pharmaceutical dispensing software of major pharmacies, including RiteAid.

61. Upon information and belief, Phenohytro also appears or will soon appear on insurance formularies as an FDA-approved generic for DONNATAL.

62. The Drug Databases are subscription-based drug information and interactions compendia used nationwide by health care professionals, insurers, payers and pharmaceutical manufacturers and others to evaluate medications that are currently on the market.

63. The Drug Databases are also used to determine whether generic substitutes are available for brand name products.

64. Upon information and belief, pharmaceutical products that are labeled as pharmaceutically equivalent are "linked" to one another in the Drug Databases.

65. Pharmaceutical equivalence means that the products contain the same active ingredients, in the same amounts, and in the same dosage forms.

66. According to their labels and package inserts, the B-Donna products and the Phenohytro products contain the same active ingredients, in the same amount, and in the same dosage form as DONNATAL.

67. Upon information and belief, the labels and package inserts for the B-Donna products have been copied from the labels and package inserts for DONNATAL, including the "Indications and Usage" section, which claims that the product has been reviewed and classified by FDA.

68. The B-Donna labels and package inserts for the B-Donna products also claim that the B-Donna product is available in an elixir form. However, upon information and belief, no such product has been launched.

69. Upon information and belief, the labels and package inserts for the Phenohytro products have also been copied from the labels and package inserts for DONNATAL.

70. Upon information and belief, Defendants have developed multiple versions of package inserts for the Phenohytro products.

71. Upon information and belief, one version falsely and misleadingly claims that "Phenohytro™ Tablets are indicated for use as adjunctive therapy in

the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis," when in fact they are not.

72. Upon information and belief, another version of Defendants' package inserts for the Phenohytro products include DONNATAL's "Indications and Usage" section and thereby represent that the product has been reviewed and classified by FDA, when in fact it has not.

73. Upon information and belief, the labels and package inserts for the B-Donna and Phenohytro products contain numerous false or misleading, or false and misleading, representations, including that the product has been reviewed or classified by FDA and/or indicated for certain uses.

74. Upon information and belief, based upon the representations on the products' labels and package inserts, the B-Donna products and the Phenohytro products have become "linked" to DONNATAL in the Drug Databases.

75. Indeed, on March 7, 2016, Defendant Pressman received an email confirming that the Phenohytro products have been "linked" to DONNATAL in the Drug Databases.

76. The "linking" of products within the Drug Databases is used by pharmacies, pharmacists, wholesalers, pharmaceutical buyers, and insurance

companies and others to determine whether there are any generic alternatives available for a particular brand product.

77. Based upon the listing and linking of the products in the Drug Databases, these relevant market players believe that the linked pharmaceutical products are FDA-approved generic equivalents that are substitutable for the brand name product.

78. Upon information and belief, these relevant market players, including wholesalers, distributors, pharmacies, pharmacists, insurers and others, are being deceived into believing that the B-Donna products, and now the Phenohytro products, are FDA-approved drugs and that they are therapeutically equivalent and/or A-rated "generics" that are substitutable for DONNATAL.

79. Notwithstanding Defendants' advertising and promotion efforts, the B-Donna products and Phenohytro products are not FDA-approved or reviewed "generics" that are therapeutically equivalent and/or A-rated to and/or substitutable for DONNATAL.

80. In addition, by listing the B-Donna and Phenohytro products on the Drug Databases after September 19, 2011, when the FDA unequivocally made

approval for new products entering the market mandatory, Defendants are misleading consumers that their products have been approved by the FDA.

81. In order to be listed in the Drug Databases, an applicant must normally submit an FDA Approval Letter and the corresponding approval number.

82. The FDA would not have provided an Approval Letter or approval number to Defendants because the Defendants do not have an approved NDA or ANDA for their drug products, nor are they participants in the FDA's DESI review process for PBA products.

83. Upon information and belief, Defendants falsely or misleadingly represented to the Drug Databases that FDA Approval Letters are not required for B-Donna or Phenohytro products to induce the Drug Databases to list and link the products to DONNATAL.

84. Defendants' listings of their B-Donna products and Phenohytro products with the Drug Databases and DailyMed have been made available to Plaintiff's customers in this District and have adversely impacted Plaintiff's sales of their DONNATAL products in this District.

85. Upon information and belief, Defendants' copying of Plaintiff's drug labels and product inserts was not done as part of a submission to the FDA or other

government agency, nor was it permitted or contemplated under any legislative provision authored by Congress.

86. The false or misleading information on the B-Donna and Phenohytro drug labels and product inserts and the listings of the B-Donna and Phenohytro products with the Drug Databases and FDA through its DailyMed website have been transmitted to customers throughout the United States.

87. Plaintiff will suffer an immediate and further substantial loss in market share as a direct result of the unauthorized entry of B-Donna or Phenohytro onto the market and Defendants' false or misleading, or false and misleading, representations regarding the B-Donna and Phenohytro products.

88. Upon information and belief, wholesalers and pharmacies have or will reduce inventories of DONNATAL as a result of the marketing or launch of the B-Donna or Phenohytro products.

89. Upon information and belief, believing B-Donna or Phenohytro to be an FDA-approved generic alternative that is substitutable for DONNATAL, pharmacists are or will automatically substitute B-Donna or Phenohytro for DONNATAL when he or she receives a prescription for DONNATAL.

90. As a result, patients will be exposed to a drug that has not been reviewed or safety-approved by the FDA. Besides the threat to public health, adverse effects may be attributed to DONNATAL because patients are often unaware of the substitution, thus resulting in the erosion of Plaintiff's goodwill or damage towards Plaintiff's commercial interests.

91. Defendants' promotion, marketing and listing of the B-Donna and Phenohytro products as a generic alternative to and substitutable for DONNATAL products, and their drug labels and product inserts, are false or misleading, or false and misleading, and have caused irreparable injury to Plaintiff and will continue to both damage Plaintiff and to deceive and potentially harm the public unless enjoined by this Court.

92. Plaintiff has been and will be harmed by Defendants' false or misleading, or false and misleading, representations. Defendants' efforts have and will continue to mislead consumers into believing that B-Donna or Phenohytro is an FDA-approved "generic" that may be automatically substituted for DONNATAL.

93. Defendants' efforts have harmed and will continue to harm Plaintiff's extensive goodwill and unique brand, as purchasers of PBA pharmaceuticals have

come to recognize Plaintiff as the only entity currently allowed to market PBA pharmaceuticals.

94. Upon information and belief, Defendants are aware or should reasonably be aware of the contractual relationships that Plaintiff maintains with pharmaceutical manufacturers, distributors and/or suppliers in order to make and sell DONNATAL, and the economic benefits to Plaintiff that flow from these relationships.

95. Upon information and belief, Defendant Pressman directed, sanctioned, actively participated in, and voluntarily and intentionally caused the above-mentioned unlawful conduct by the corporate Defendants.

COUNT I

FALSE ADVERTISING IN VIOLATION OF LANHAM ACT SECTION 43(a)(1)(B) (15 U.S.C. § 1125(a)(1)(B))

96. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Amended Complaint, and incorporates them herein by reference.

97. Defendants' commercial advertising and promotion of the B-Donna and Phenohytro products, including the placement of false or misleading, or false

and misleading, information on the Drug Databases and the marketing of its products as comparable to, equivalent to, or alternative for DONNATAL, constitute false or misleading, or false and misleading, descriptions or representations of fact that the B-Donna or Phenohytro products are FDA-approved "generic" products that are therapeutically equivalent or A-rated to and/or substitutable for DONNATAL.

98. Upon information and belief, the labels and package inserts for the B-Donna and Phenohytro products also contain numerous false or misleading, or false and misleading, representations, including that the product has been reviewed or classified by FDA and is indicated for certain uses.

99. Defendants' statements have actually deceived or have the tendency to deceive a substantial segment of their audience as to the nature, quality, and characteristics of the B-Donna or Phenohytro products.

100. Defendants' false or misleading, or false and misleading, claims about the B-Donna or Phenohytro products are material and likely to influence the purchasing decisions of wholesalers, third-party payors, pharmacists, health care professionals, insurers, prescribers, and others in the pharmaceutical industry, as well as patients or caregivers of patients who consume Plaintiff's products.

101. Defendants' false or misleading, or false and misleading, representations were and are made in interstate commerce.

102. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered and is continuing to suffer irreparable injury, including irreparable injury and damages, which includes a loss of sales, profits, and customers, which Plaintiff would have but for the false or misleading, or false and misleading, representations by Defendants.

103. Pursuant to 15 U.S.C. § 1116, Plaintiff is entitled to preliminary and permanent injunctive relief to Defendants' continuing acts.

104. Pursuant to 15 U.S.C. § 1117, Plaintiff is entitled to recover all damages sustained by Defendants' actions, an accounting for profits realized by Defendants through their false or misleading, or false and misleading, advertising of the B-Donna or Phenohytro products, and the costs of this action.

105. Defendants' actions have been willful and deliberate, entitling Plaintiff to recover treble damages and/or profits. In addition, as this is an exceptional case pursuant to 15 U.S.C. § 1117(a), Plaintiff is entitled to an award of reasonable attorneys' fees.

COUNT II

CONTRIBUTORY FALSE ADVERTISING IN VIOLATION OF LANHAM ACT SECTION 43(a)(1)(B) (15 U.S.C. § 1125(a)(1)(B))

106. Plaintiff repeats and re-alleges each and every allegation contained in the proceeding paragraphs of this Amended Complaint, and incorporates them herein by reference.

107. Upon information and belief, Defendants are knowingly inducing or causing, and/or materially participating in, the false or misleading, or false and misleading, advertising and promotion of the B-Donna or Phenohytro products by Drug Databases, pharmacies, and/or other members of the pharmaceutical industry as FDA-approved "generic" products that are therapeutically equivalent or A-rated to and/or substitutable for DONNATAL.

108. Upon information and belief, Defendants knew and/or intended to participate in the false advertising of the B-Donna or Phenohytro products by Drug Databases, pharmacies, insurers, and/or other members of the pharmaceutical industry.

109. Upon information and belief, Defendants actively and materially furthered such false or misleading, or false and misleading, advertising and

promotion of the B-Donna or Phenohytro products by making false or misleading, or false and misleading, representations about the products on their labels and product inserts, making false or misleading, or false and misleading representations to the Drug Databases to list the B-Donna or Phenohytro products with the Drug Databases, listing the products with the Drug Databases, and/or marketing the products as "generics" that are comparable to and/or substitutable for DONNATAL.

110. Such false or misleading, or false and misleading, statements about the B-Donna or Phenohytro products by Drug Databases, pharmacies, insurers and/or other members of the pharmaceutical industry have actually deceived or have the tendency to deceive a substantial segment of their audience as to the nature, quality, and characteristics of the B-Donna or Phenohytro products.

111. Such false or misleading, or false and misleading statements about the B-Donna or Phenohytro products by Drug Databases, pharmacies, and/or other members of the pharmaceutical industry are material and likely to influence the purchasing decisions of wholesalers, third-party payors, pharmacists, health care professionals and others in the pharmaceutical industry, as well as patients who consume Plaintiff's products.

112. These false or misleading, or false and misleading, representations were and are made in interstate commerce.

113. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered damages, which includes a loss of sales, profits and customers, which Plaintiff would have made but for the false and deceptive representations by Defendants.

114. Defendants' actions as alleged herein have caused, are causing, and will continue to cause irreparable and inherently unquantifiable injury and harm to Plaintiff's business, reputation, and goodwill, unless Defendants' unlawful conduct is enjoined by this Court.

115. Pursuant to 15 U.S.C. § 1116, Plaintiff is entitled to preliminary and permanent injunctive relief to Defendants' continuing acts.

116. Pursuant to 15 U.S.C. § 1117, Plaintiff is entitled to recover all damages sustained by Defendants' actions, an accounting for profits realized by Defendants, and the costs of this action.

117. Defendants' actions have been willful and deliberate, entitling Plaintiff to recover treble damages and/or profits. In addition, as this is an exceptional case

pursuant to 15 U.S.C. § 1117(a), Plaintiff is entitled to an award of reasonable attorneys' fees.

COUNT III

TRADEMARK INFRINGEMENT IN VIOLATION OF LANHAM ACT SECTION 32 (15 U.S.C. § 1114)

118. Plaintiff repeats and re-alleges each and every allegation contained in the proceeding paragraphs of this Complaint, and incorporates them herein by reference.

119. The B-Donna mark is a colorable imitation of Plaintiff's federally-registered DONNATAL mark and Defendants' unauthorized use of the B-Donna mark in commerce in connection with the sale, offering for sale, distribution, and/or advertisement of its competing pharmaceutical products is likely to cause confusion, cause mistake, and/or deceive prospective or actual customers and other members of the public.

120. Upon information and belief, the B-Donna product continues to be listed on the Drug Databases, pharmacy computers, formularies, and other marketing channels.

121. Upon information and belief, Defendants' purpose in using the B-

DONNA mark was and is to deceive, mislead and confuse customers, so as to trade on the substantial reputation and goodwill enjoyed by Plaintiff in connection with the DONNATAL mark.

122. Defendants' adoption and unauthorized use of the B-Donna mark infringes Plaintiff's exclusive rights in its federally registered DONNATAL mark in violation of Section 32, 15 U.S.C. § 1114, of the Lanham Act.

123. Defendants' acts of infringement as alleged herein have caused, are causing, and will continue to cause irreparable and inherently unquantifiable injury and harm to Plaintiff's business, reputation, and goodwill, unless Defendants' unlawful conduct is enjoined by this Court.

124. Plaintiff is entitled to recover all damages sustained by Defendants' actions, all profits realized by Defendants through their infringing use of the DONNATAL mark, and the costs of this action.

125. Defendants' actions have been willful and deliberate, entitling Plaintiff to recover treble damages and/or profits. In addition, as this is an exceptional case pursuant to 15 U.S.C. § 1117(a), Plaintiff is entitled to an award of reasonable attorneys' fees.

COUNT IV

UNFAIR COMPETITION IN VIOLATION OF LANHAM ACT SECTION 43(a)(1)(A) (15 U.S.C. § 1125(a)(1)(A))

126. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Amended Complaint, and incorporates them herein by reference.

127. Upon information and belief, Defendants' use of the B-Donna mark and the false or misleading, or false and misleading, information on the product labels, package inserts, and other marketing materials for the B-Donna or Phenohytro products have caused and are likely to continue to cause confusion, mistake, and/or deceive prospective or actual customers and other members of the public as to the source, origin, sponsorship or approval of Defendants' products and/or its affiliation, connection, or association with Plaintiff.

128. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered damages, which includes a loss of customers, sales and profits, which Plaintiff would have but for the false or misleading, or false and misleading, representations by Defendants.

129. Defendants' actions as alleged herein have caused, are causing, and will continue to cause irreparable and inherently unquantifiable injury and harm to Plaintiff's business, reputation, and goodwill, unless Defendants' unlawful conduct is enjoined by this Court.

130. Pursuant to 15 U.S.C. § 1116, Plaintiff is entitled to preliminary and permanent injunctive relief to Defendants' continuing acts.

131. Pursuant to 15 U.S.C. § 1117, Plaintiff is entitled to recover all damages sustained by Defendants' actions, an accounting for profits realized by Defendants, and the costs of this action.

132. Defendants' actions have been willful and deliberate, entitling Plaintiff to recover treble damages and/or profits. In addition, as this is an exceptional case pursuant to 15 U.S.C. § 1117(a), Plaintiff is entitled to an award of reasonable attorneys' fees.

COUNT V

COMMON LAW UNFAIR COMPETITION

133. Plaintiff repeats and re-alleges each and every allegation contained in the proceeding paragraphs of this Amended Complaint, and incorporates them herein by reference.

134. Defendants have made false or misleading, or false and misleading, statements to the marketplace, public and actual or potential customers and have mislabeled the B-Donna and Phenohytro products with the intent of deceiving and misleading the public as to the quality and nature of its product.

135. The aforesaid acts have enabled Defendants to misappropriate the labors and expenditures of Plaintiff in researching, developing, and educating the market for DONNATAL.

136. Additionally, the aforesaid acts have caused, and are likely to continue to cause injury to the public and to Plaintiff's customers' sales, business reputation, and result in Defendant unfairly competing with Plaintiff.

137. As a direct and proximate result of Defendants' conduct, Plaintiff has suffered damages, which includes a loss of sales, profits and customers, which Plaintiff would have but for the false or misleading, or false and misleading, representations by Defendants.

COUNT VI

VIOLATIONS OF THE GEORGIA UNIFORM DECEPTIVE PRACTICES ACT

138. Plaintiff repeats and re-alleges each and every allegation contained in

the proceeding paragraphs of this Amended Complaint, and incorporates them herein by reference.

139. O.C.G.A. § 10-1-372 provides that:

> (a) A person engages in a deceptive trade practice when, in the course of his business, vocation, or occupation, he:
> (1) passes off goods or services as those of another;
> (2) causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;
> (3) causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another;
> ...
> (5) represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have or that a person has a sponsorship, approval, status, affiliation, or connection that he or she does not have;
> ...
> (7) represents that goods or services are of a particular standard, quality, or grade, or that goods are of a particular style or model, if they are of another;
> ...
> (12) Engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

140. O.C.G.A. § 10-1-373 provides a private right of action to enforce the provisions of O.C.G.A. § 10-1-372.

141. In the course of their business, Defendants, by and through their infringing use of the B-Donna mark and their false or misleading, or false and misleading, representations of fact and conduct concerning the B-Donna or

Phenohytro products, have engaged in and continue to engage in deceptive trade practices in violation of O.C.G.A. § 10-1-372.

142. Defendants have willfully engaged in these actions, knowing them to be deceptive.

143. By reason of Defendants' conduct, Plaintiff has suffered and will continue to suffer damage to its business, reputation and goodwill.

144. Pursuant to O.C.G.A. § 10-1-373, Plaintiff is entitled to enjoin Defendants' unlawful conduct as well as recover reasonable attorneys' fees.

145. As a proximate result of Defendants' misrepresentations, Defendants' conduct has caused, and unless enjoined by this Court, will continue to cause immediate and irreparable harm, for which Plaintiff is entitled to injunctive relief and damages in an amount to be proven at trial.

COUNT VII

COMMON LAW UNJUST ENRICHMENT

146. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Amended Complaint, and incorporates them herein by reference.

147. Defendants' unauthorized use and copying of Plaintiff's DONNATAL labels; Defendants' listing of the unauthorized B-Donna or Phenohytro products with the Drug Databases and FDA; Defendants' misrepresentations that their B-Donna or Phenohytro products are FDA-approved "generics" that are equivalent to and/or substitutable for Plaintiff's DONNATAL; and/or the Defendants' marketing, manufacture and sale of the B-Donna or Phenohytro products without license or authorization of Plaintiff are benefits conferred on and inequitably retained by Defendants.

148. Defendants knew of the above-listed benefits because these benefits were the result of Defendants' unauthorized and illegitimate actions.

149. These benefits were valuable to Defendants and Defendants should have reasonably expected to repay Plaintiff for these benefits, for at least the reason that any such benefits would have only been conferred on Defendants through a bargained-for license agreement from Plaintiff.

150. Defendants accepted or retained these benefits without paying Plaintiff for their value. Defendants' receipt of the benefits without compensation to Plaintiff would be unjust.

COUNT VIII

TORTIOUS INTERFERENCE WITH CONTRACT OR BUSINESS RELATIONSHIPS

151. Plaintiff repeats and re-alleges each and every allegation contained in the preceding paragraphs of this Amended Complaint, and incorporates them herein by reference.

152. Defendants are aware of Plaintiff's valid contractual and business relationships with manufacturers, distributors and/or suppliers that are maintained in order to make and sell DONNATAL.

153. Defendants are aware of the economic benefits that flow to Plaintiff as a result of these contractual relationships. Defendants are further aware of the probability that economic benefits would continue to flow to Plaintiff in the future as a result of these contractual relationships.

154. Defendants' wrongful and intentional conduct as set forth in this Amended Complaint has interfered with Plaintiff's valid contractual relationships.

155. Upon information and belief, Defendants' wrongful and intentional conduct has caused third parties to discontinue or fail to enter into anticipated relationships with Plaintiff.

156. Defendants' conduct has proximately caused damage to Plaintiff in the form of lost sales, prescriptions and customers, and has thereby caused the diminution and erosion of the current and future economic benefits that flow from Plaintiff valid contractual relationships.

157. There is a reasonable certainty that absent Defendants' intentional conduct, Plaintiff would have realized the full economic benefits of their contractual relationships.

JURY DEMAND

Plaintiff demands a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that the Court enter judgment in their favor and grant the following relief:

A. Compensatory damages, consisting of general and special damages, in an amount to be proven at trial;

B. An award of punitive damages;

C. A preliminary and permanent injunction enjoining Defendants, and all others acting in privity or in concert with them, from listing, linking, marketing, offering for sale, or selling the B-Donna or Phenohytro products, or any other unauthorized

pharmaceutical product containing the same active ingredients as DONNATAL;

D. A preliminary and permanent injunction enjoining Defendants, and all others acting in privity or in concert with them, from listing the B-Donna or Phenohytro products, or any other unauthorized pharmaceutical product containing the same active ingredients as DONNATAL, in the industry price lists, including Medi-Span and First Databank, and from further advertising or marketing the B-Donna or Phenohytro products using any false or misleading, or false and misleading, statements,

E. Cancellation of U.S. Reg. No. 4,883,086 pursuant to 15 U.S.C. § 1119;

F. Reasonable attorney fees and costs in prosecuting this action as provided by § 35(a) of the Lanham Act, 15 U.S.C. § 1117 and Georgia law; and

G. Award Plaintiff such other relief as the interests of justice may require.

DATE: March 24, 2016 Respectfully submitted,

CONCORDIA PHARMACEUTICALS INC., S.À.R.L.

BY: s/ W. Brian Holladay
W. Brian Holladay
Georgia Bar No. 300576
Martenson, Hasbrouck & Simon LLP
3379 Peachtree Road, N.E. Suite 400
Atlanta, Georgia 30326
Tel. (404) 909-8100

Fax: (404) 909-8120
bholladay@martensonlaw.com

S. Lloyd Smith (*pro hac vice*)
Aaron L. J. Pereira
Laura K. Pitts
James T. Wilcox
BUCHANAN INGERSOLL & ROONEY PC
1737 King Street, Suite 500
Alexandria, Virginia 22314
Tel. (703) 836-6620
Fax: (703) 836-2021
lloyd.smith@bipc.com
aaron.pereira@bipc.com
laura.pitts@bipc.com
james.wilcox@bipc.com

Attorneys for Plaintiff Concordia Pharmaceuticals, Inc. S.À.R.L.

CERTIFICATION OF FONT SIZE

Pursuant to Local Rule 5.1(B) of the Local Rules of the United States District Court for the Northern District of Georgia, I, W. Brian Holladay, Esq., of Martenson, Hasbrouck & Simon LLP, attorneys for Plaintiff Concordia Pharmaceuticals Inc., S.À.R.L., hereby certify that the foregoing is typewritten using Times New Roman font, fourteen (14) point type.

MARTENSON, HASBROUCK & SIMON LLP

BY: s/W. Brian Holladay
W. Brian Holladay
Georgia Bar No. 300576
3379 Peachtree Road N.E. Suite 400
Atlanta, Georgia 30326
(404)-909-8100 (telephone)
(404)-909-8120 (facsimile)
bholladay@martensonlaw.com

Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF GEORGIA
Gainesville Division

CONCORDIA PHARMACEUTICALS INC., S.À.R.L. *Plaintiff*, v. WINDER LABORATORIES, LLC and STEVEN PRESSMAN *Defendants*.	:	C.A. No. 2:16-cv-00004-RWS Jury Trial Demanded

CERTIFICATE OF SERVICE

I hereby certify that a true and correct copy of the foregoing was served electronically via the Court's ECF system to the counsel of record in this lawsuit.

This 24th day of March 2016.

BY: /s/ W. Brian Holladay
W. Brian Holladay